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## CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICES: SHARED CARE GOALS OF MONITORING AND TREATING PATIENTS

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#### **Abstract**

Continuous-flow left ventricular assist devices (CF-LVADs) have been clinically adopted as a long-term standard of care therapy option for patients with end-stage heart failure. For many patients, shared care between the care providers at the implanting center and care providers in the community in which the patient resides is a clinical necessity. The aims of this review are to (1) provide a rationale for the outpatient follow-up exam and surveillance testing used at our center to monitor patients supported by the HeartMate II® CF-LVAD (Thoratec Corporation, Pleasanton, CA) and (2) provide the protocol/algorithms we use for blood pressure, driveline exit site, LVAD alarm history, surveillance blood work, and echocardiography monitoring in this patient population. In addition, we define our partnership outpatient follow-up protocol and the "shared care" specific responsibilities we use with referring health care providers to best manage many of our patients.

### Introduction

Over the past several years, axial and more recently centrifugal continuous-flow left ventricular assist devices (CF-LVADs) have become the devices of choice as bridge-to-transplantation or destination therapy due to significantly improved outcomes and fewer complications in patients with end-stage heart failure (Table 1).¹ Historically, referring physicians and/or other care providers have deferred the bulk of post-CF-LVAD surveillance and management decisions to the implanting LVAD center heart team. With an increasing population of patients supported by CF-LVADs, especially as destination therapy with anticipated long-term support, the concept of "shared care" has evolved in the heart failure community. Shared care in part refers to the cared

shared between the care providers at the implanting center and those in the community in which the patient resides. In our patient population, patients may live several hundred miles from our center, making frequent follow-up challenging due to travel and economic demands. Some of the other proposed benefits of shared care are listed in Table 2.

This manuscript provides the rationale behind our outpatient follow-up exam at Houston Methodist Hospital and the surveillance testing used to monitor patients supported by the HeartMate II® CF-LVAD (Thoratec Corporation, Pleasanton, CA) (Figure 1). It also describes the protocol/algorithms we use for blood pressure (BP), driveline exit site, LVAD alarm history, surveillance blood work, and echocardiography monitoring in

CF-LVAD types	Approved indications	Pump design/ location	Pump speed range/ typical speed (rpm)	Anticoagulation recommendation	Device illustration
2nd generation HeartMate II	Bridge to heart transplantation	Axial/ preperitoneal	6,000-15,000/8800-9200	Aspirin 81-325 mg	
	Destination therapy			Coumadin (INR 2-3)	T. T.
3rd generation HeartWare HVAD	Bridge to heart transplantation	Centrifugal/ intrapericardial	1800-4,000/2600-2900	Aspirin 81-325mg	
				Coumadin (INR 2-3)	

Table 1. Approved adult durable continuous-flow left ventricular assist device types and characteristics. Photos reprinted with permission from Heartmate II (Thoratec Corp.) and HeartWare, Inc, Framingham, MA.

Permits the patient to maintain his/her established relationship with the referring health care provider.

Makes follow-up easier for some patients and/or caregivers (family and friends) from a convenience and economic perspective (less travel and less expensive), which may equate to improved compliance with recommended follow-up.

Empowers the referring health care provider to deliver reliable long-term outpatient care in accord with established best practice (defined by the implanting center).

Provides the referring health care provider with a knowledge/clinical skill-set foundation to address urgent/emergent inpatient issues.

Positions the referring health care provider to serve as the provider/champion for emergent community care services that may be needed in patients supported by CF-LVAD.

Table 2. Benefits of establishing shared care responsibilities between the implanting left ventricular assist device (LVAD) center and the referring heath care provider/s.

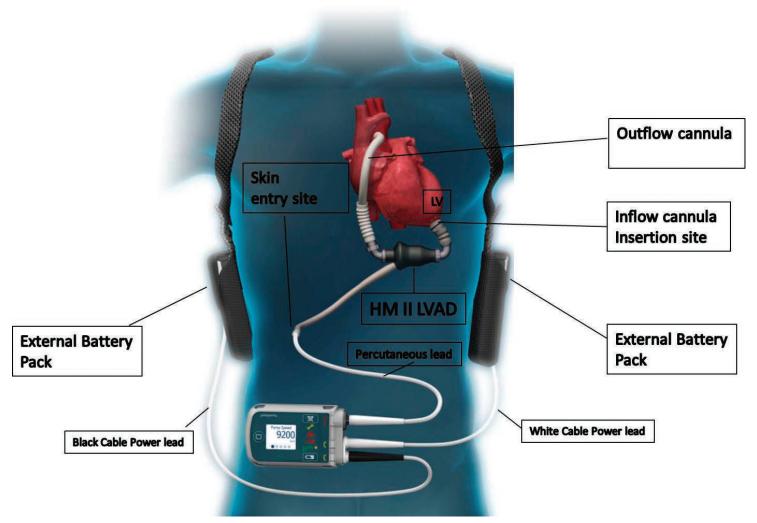


Figure 1. HeartMate II device and equipment illustration. HM: HeartMate II; LVAD: left ventricular assist device; LV: left ventricle.

this patient population. In addition, we define our partnership outpatient follow-up protocol and the shared care-specific responsibilities we use with referring health care providers to best manage many of our patients.

### **Blood Pressure Monitoring**

In addition to documenting routine vitals, careful BP assessment is necessary to minimize adverse events in patients supported with a CF-LVAD. It is critical for the provider to

not only be familiar with BP goals in these patients but also understand the intricacies of measuring their BP. There are several advantages of maintaining BP in patients supported by CF-LVADs, including optimization of device pump function since all devices are sensitive to excess afterload (centrifugal devices to a greater extent than axial flow devices), optimization of LV unloading, minimizing left-sided heart failure symptoms, and preventing both hemorrhagic and nonhemorrhagic strokes.<sup>2</sup> According to the most recent International Society of Heart and Lung Transplant (ISHLT)

# Measurement of Blood Pressure

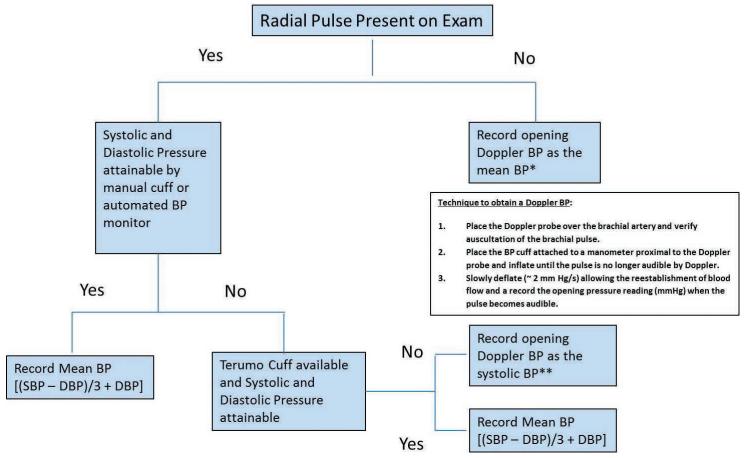


Figure 2. Measurement of blood pressure (BP) in patients on CF-LVADs.

\*Doppler BP may be a slight overestimation compared to arterial line mean BP measurements.

guidelines, mean BP in patients supported by CF-LVADs should be less than or equal to  $80~\rm mm$  Hg with a typical goal range between  $70~\rm and~80~\rm mm$  Hg.  $^3$ 

In many patients, CF-LVADs are associated with a reduced pulse pressure, and the degree of this diminished pulsatility depends on the pump speed setting, underlying LV contractility, and preload and afterload pressures. The aortic valve in some patients may be open at a baseline set speed, but as the pump speed (revolutions per minute) is increased, the diastolic pressure increases to a point that exceeds the pressure gradient across the aortic valve (AV). This results in cessation of AV opening and a significantly reduced pulse pressure, which clinically equates to no palpable radial pulse. Patients supported by CF-LVADs may have complete AV opening (palpable pulse), absent AV opening (no palpable pulse), or partial and/or intermittent AV opening (intermittent and weak palpable pulse). Even at a fixed speed, the presence and degree of AV opening is dynamic and may change from one clinic visit to the next.

Due to the reduced pulse pressure common in this patient population, it can be difficult to record BP using traditional measurements (auscultation or automated cuff) because of the sensitivity range associated with these standard methods. In general, success rates in using automated BP monitors to obtain a BP in patients on CF-LVAD range between 17% and 63%.  $^{46}$  The current recommendation is to use a Doppler ultrasound probe that detects flow at any point during the cardiac cycle and measures an opening pressure in almost all CF-LVAD patients, with success rates between 94% and 100%.  $^{4.5}$ 

In a sample of 17 patients supported by a HeartMate II LVAD, Bennett et al. reported that the mean difference between Doppler and arterial-line mean arterial pressure (MAP) was  $0.2 \pm 10.5$  mm Hg compared with a mean difference between Doppler and arterial-line systolic BP of  $8.6 \pm 9.5$  mm Hg, thus suggesting that Doppler BP values more closely represent the true MAP as opposed to true systolic BP.4 In contrast, Lanier et al. demonstrated in 60 patients supported by the HeartMate II that the Doppler BP underestimates systolic BP by  $4.1 \pm 1.5$  mm Hg and overestimates mean arterial BP by  $9.5 \pm 1.9$  mm Hg, suggesting that Doppler better reflects systolic BP.5 For practical purposes, in patients with a significantly reduced pulse pressure (no palpable radial pulse), the recorded opening Doppler blood pressure reflects the systolic BP and approximates the mean BP.

<sup>\*\*</sup>Doppler BP may be a slight underestimation compared to arterial line systolic BP measurements. BP: blood pressure; SBP: systolic blood pressure; DBP: diastolic blood pressure.

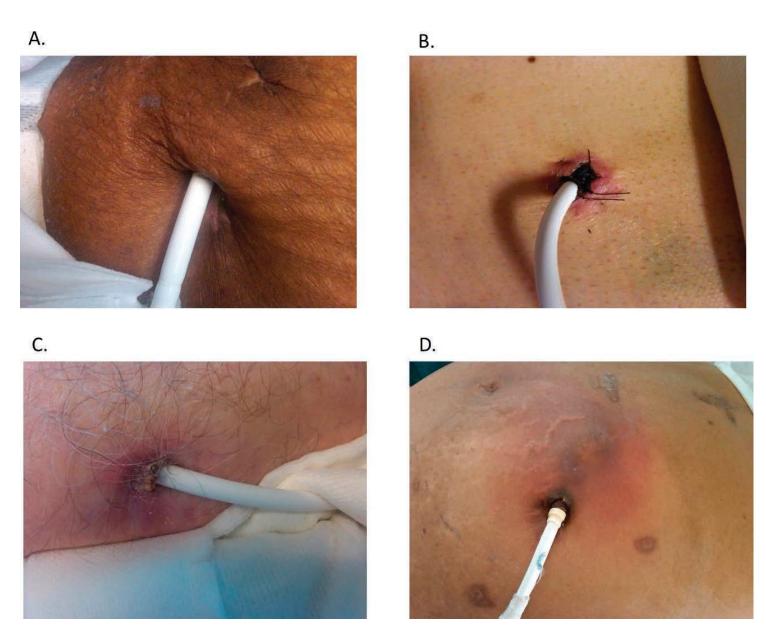


Figure 3. Driveline exit site examples showing (A) normal exit site with no associated redness or drainage; (B) mild redness around the exit site, no drainage; suture noted reflective of a recent implant (left in place for ~ 3 months); (C) mild to moderate redness with associated drainage (dry/crusted) around the exit site; and (D) extensive redness extending beyond the exit site consistent with cellulitis; typically associated with tenderness.

Based on our observations and these reports, we measure blood pressure using the algorithm illustrated in Figure 2. If a radial pulse is present (reflective of a near normal pulse pressure), the typical Korotkoff sounds are present and systolic and diastolic blood pressure in this scenario is attainable. When the BP is attainable using standard methodologies (manual BP or an automated BP monitor), the recording remains accurate compared to arterial line measurement and can therefore be used to monitor patients.<sup>4,5</sup>

An acceptable alternative to an unattainable manual or automated BP monitor is to use the Terumo Elemano BP Monitor, which was designed with a slow-deflation capability to improve the sensitivity of BP measurements in patients with a reduced pulse pressure. Lanier et al. demonstrated that the Terumo Elemano BP Monitor was successful (91% success rate to attain BP reading), reproducible, and valid when compared with A-line (gold standard) and Doppler (clinical standard).

An understanding of these important clinical nuances to BP monitoring in patients with CF-LVADs can curb outpatient overutilization of vasoactive medications to avoid adverse side effects of hypotension, which can manifest as dizziness or syncope. For those patients with true hypertension (mean BP > 80 mm Hg), the treatment recommendation is similar to the recommend use of agents indicated for heart failure patients.<sup>3</sup> These include angiotensin converting enzymes or angiotensin receptor blockers and beta blockers. In a study by Lampert et al., 74% of patients who had received CF-LVAD required antihypertensive medications when using the commonly cited goal mean BP of less than 80 mm Hg. Of these, 88% required one or two antihypertensive medications, with no difference between axial and centrifugal flow devices in the percentage of those requiring BP mediations.8 The early initiation of betaadrenergic receptor blockade in patients with a preimplant history of ventricular tachycardia or with early postimplant

### A. HeartMate II Console

### B. System Monitor



### C. System Monitor History Display

	Settings		Varms	Sava	Liana	History	Admir
MY-TIME	FUNE PUNE FLOW SPEED	PUMP	PHILSE	MLARH.			
03/21/14 18:29:52	10.4 8980	10.2	1.3	PI Event			
03/21/14 16:27:31	9.8 8960	11.3	5.8	PI Event			
03/21/14 15:52:23	8.5 8940	7.0	8.1	Power Cable	Discor	nected	
03/21/14 15:52:02	10.7 8980	8.0	1.7	Power Cable	Discon	nected	
03/21/14 15:50:39	8.1 8990	9.9	6.4	PI Event			
93/21/14 12:45:46	11.1 8980	9.2	1.9	PI Event			
03/21/14 06:00:32	4.9 8910	1.9	8.4	Power Cable	Discon	nected	
03/21/14 05:59:36	4.7 8920	1.9	8.1	Power Cable	Discon	nected	
03/20/14 21:01:51	5.5 8950	5.0	8.0	Power Cable	Discon	nected	
03/20/14 21:00:24	5.1 8950	4.9	8.5	Power Cable	Discom	nected	
03/20/14 08:12:16	4.6 8910	4.8	9.3	Power Cable	Discom	nected	
03/20/14 08:11:20	4.4 8960	1.8	9.3	Power Cable	Discom	sected	
					Records	37 - 40 of	240

### **LVAD Baseline Parameters:**

### Flow L/min

- Speed \_\_\_\_rpm
- Pulse Index
- Power watts

### LVAD Interrogation:

Review Alarm I	nistory [	] Y	[ ]N
THE VIEW / Hallin	mocory [	4 .	L J

•	Speed drops	l	JY	L	]	N
•	Power spikes	I	] Y	1	]	Ν
•	Low Flow Alarm	1	] Y	[	]	Ν
•	PI Event	1	] Y	[	]	N
•	Pump Stops	[	] Y	ſ	1	Ν

J I have personally interrogated LVAD.
] LVAD is functioning well

Stable pump parameters

Figure 4. LVAD setting documentation/interrogation. (A) System monitor with power module (plugs into an AC outlet to provide power to the HeartMate II system) and power base unit including back up batteries. (B) System monitor displayed pump flow, pump speed, pulse index, and pump power. (C) System monitor alarm history display.

supraventricular tachycardia or ventricular tachycardia can be helpful. In keeping with heart failure guidelines, the use of heart rate-limiting calcium channel blockers is not recommended.3

### **Driveline Exit Site Inspection**

The most important factor in preventing the morbidity of infections is anchoring the device to help stabilize the driveline, thus minimizing trauma and tension at the exit site. Routine follow-up visits allow for continued education on driveline immobilization. The driveline exit site is examined for redness, drainage, tenderness, and open areas at the site. Figure 3 shows examples of a normal exit site and the variety of infections that may be seen there. When mild infections are encountered, such as scant drainage and limited redness without tenderness or induration, we obtain a culture and instruct the patient and/ or caregivers to increase the frequency of local wound care (e.g., increase dressing changes to twice per day versus once). We ensure that the patient is following a sterile dressing care regimen in accord with our protocol requiring the use of chlorhexidine with exit site daily dressing changes. In patients showing signs of a complicated exit site infection, including moderate drainage and

greater extent of redness and tenderness, additional treatment with oral antibiotics is recommended, and weekly clinic visits are planned to ensure exit site improvement. If the patient shows signs of systemic infection such as a fever greater than 101° F or an acquired leukocytosis and/or purulent drainage associated with subcutaneous induration, inpatient monitoring and treatment is recommended.

### **Outpatient LVAD Alarm Trouble Shooting**

According to the most recent ISHLT guidelines, the alarm history and downloads should be obtained at regular intervals.3 It is our practice to review and document the alarm history (Figure 4) and pump parameters with every outpatient clinic visit. In the clinic, the patient's LVAD can be connected to the system monitor to permit LVAD setting review, documentation, and device interrogation. Displayed pump flow is an estimated value directly related to the selected speed (rotary pump rotation in revolutions per minute) and power. Typically, any increase in power will result in an increase in estimated flow.

The displayed power is a direct measurement of pump motor voltage and current. Changes in pump speed, flow, or physiological demand can affect pump power. For the HeartMate

Possible VAD alarm findings*	Pulse Index (PI) decrease PI event	PI decrease PI event Low flow alarm** Flow display ""	PI decrease PI event Low flow alarm Flow display ""	PI decrease PI event Low flow alarm Flow display""	PI increase^^	PI decrease PI event Low flow alarm Flow display""	PI decrease PI event Low flow alarm Flow display ""
Possible symptoms and signs	Pre-syncope     Palpitations     Low or high CVP	1. Pre-syncope 2. Low CVP 3. Hypotension	Pre-syncope     Fatigue     Elevated CVP     Hypotension	Pre-syncope     Syncope     Elevated CVP     Hypotension     Tachycardia	1. SOB 2. Elevated CVP 3. Increased MAP	1. SOB 2. Elevated CVP	Pre-syncope     Syncope     Palpitations
Possible clinical diagnosis	LVAD suction event **	Hypovolemia	Late RV failure	Tamponade^	Severe HTN	Inflow thrombus or outflow Cannula kinking/ obstruction^^	Arrhythmias
Treatment#	Decrease pump speed Screen for underlying cause**	Stop diuretics Increase oral volume intake and/ or admit for IV normal saline bolus	Increase diuretics Optimize pump speed setting***	Pericardial Drainage	Initiate and/or up-titrate systemic vaso-dilators	Increase anti- coagulation if thrombus suspected and INR less than 2.0	Increase beta- blocker dosage Consider a rhythm control strategy

<sup>\*</sup>May be associated with or detected by the following: PI decreased, PI event, low flow alarm display, or flow display "---" noted as the flow estimate. See text for parameter descriptions.

Table 3. HeartMate II left ventricular assist device (LVAD) "low flow" alarm trouble shooting.

Possible VAD alarm findings*	Power greater than 10 watts Flow display "+++" Decreased PI PI event	Decreased pulse index (PI) or constant PI Event	PI event
Possible symptoms/signs	Dark urine/hematuria     Fatigue     Shortness of breath     Elevated CVP     Elevated LDH and/or elevated plasma free hemoglobin     Decreased hemoglobin     Elevated total bilirubin	Fatigue     Fever     Elevated white blood cell count     Decreased MAP	Fatigue     Shortness of breath     Elevated CVP
Possible clinical diagnosis	Rotor/Bearing Thrombosis	Sepsis syndrome or Medication vasodilation effect	Significant aortic regurgitation
Treatment#	Enhance anticoagulation Screen for device pump malfunction**	Screen for underlying infection Hold hypertension medications	Up-titrate diuretics If refractory symptoms of congestion, right heart catheterization to tailor optimal pump speed

<sup>\*</sup> Heartmate (HM)II feature-PI=Pulsatility Index is the left ventricle's pulsatile contribution to the pump; PI event occurs when there is a 45% + or - change from the previous 15 second running average.
\*\*Echo speed change protocol as detailed in reference (11).

Table 4. HeartMate II left ventricular assist device (LVAD) "high flow" (high power) alarms.

Are you experiencing shortness of breath and/or leg swelling?	(Left- and/or right-sided heart failure)
Have you noticed the development of dark urine?	(Acquired hemolysis and rotor pump thrombosis)
Are you experiencing fatigue?	(Heart failure and/or hemolytic anemia and/or acute blood loss anemia and gastrointestinal (GI) bleeding
Have you experienced darker and/or bloody stools?	(GI bleeding secondary to acquired arteriovenous malformations)
Have you noticed drainage and/or pain around your driveline exit site?	(LVAD-related infection)
Have you experienced fever and/or chills?	(LVAD-related infection)
Have you experienced any alarms? If so, what kind?	(see Table 3 and 4 for differential)
Have you had any incidence of trauma to driveline?	(Driveline fracture)

Table 5. Left ventricular assist device (LVAD)-specific review of symptoms and possible underlying diagnosis.

LVAD suction event can be seen with hypovolemia, RV failure, and tamponade and may be associated with arrhythmyias (atrial and/or ventricular) and inflow cannula malposition.

<sup>\*\*\*</sup>Optimization of pump speed setting using echocardiography and right heart catheterization with the possible use of intravenous inotropes should be performed by the implanting LVAD center heart team

<sup>^</sup> Very infrequent diagnosis in the outpatient setting.

<sup>^^</sup>Variable power/flow and PI changes can be seen depending on severity of hypertension

<sup>#-</sup>The above findings and suspected clinical diagnosis and planned treatment should be discussed and reviewed with the LVAD implanting center heart team PI=pulsatility index; CVP=central venous pressure; SOB=shortness of breath; MAP=mean arterial pressure; LVAD=left ventricular assist device; HTN=hypertension; IV=intra-venous; INR=international normalized ratio

<sup>#</sup> The above findings and suspected clinical diagnosis and planned treatment should be discussed and reviewed with the LVAD implanting center heart team CVP=central venous pressure; SOB=shortness of breath; MAP=mean arterial pressure; LVAD=left ventricular assist device

In addition to documentation of standard demographics, annotate device type and pump speed setting in revolutions per minute for continuous-flow devices.

Standard comprehensive echocardiography examination should be performed in any heart failure patient in accord with ASE guidelines.

### Special considerations

- 2-dimensional (2D) and M-mode using 3 to 5 cardiac cycles for the following:
  - a) Parasternal long- and short-axis views evaluation to assess ventricular dimensions/function.
  - b) Aortic valve opening frequency with report documentation as opens with every cardiac cycle or as partial and/or intermittent or as no AV opening seen (see Figure 5).
  - c) Inflow cannula views: Use standard and "off axis" 4- and 2-chamber apical views, parasternal long- (mid-level) and apical-parasternal long-axis view ("modified apical"). Obtain 2D, color, and spectral Doppler from view with the best alignment. Report flow characteristics (normal flow direction, turbulent versus nonturbulent flow, and peak systolic and diastolic velocity) to delineate normal from obstructive flow patterns (see Figure 6).
  - d) Outflow cannula views: Right parasternal (low- and mid-level) view. Obtain 2D, color, and spectral Doppler and report flow characteristics similar to the inflow cannula examination.

Table 6. Continuous-flow left ventricular assist device echocardiogram imaging protocol and reporting.

Α

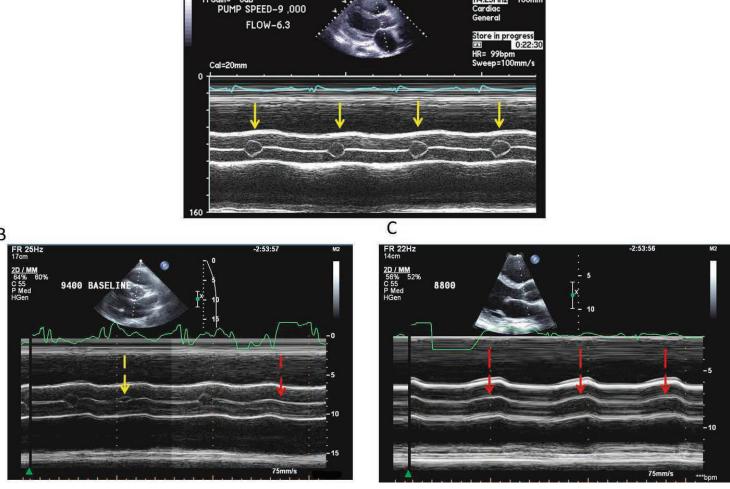


Figure 5. Echocardiographic aortic valve function assessment during continuous-flow left ventricular assist device (CF-LVAD) support. Various degrees of aortic valve (AV) opening with CF-LVAD support. M-mode images of aortic valve (AV) opening patterns in three different patients with HeartMate II devices. (A) Normal, consistent AV opening (solid yellow arrow). (B) Intermittent and variable partial AV opening (broken yellow arrow) and closure (broken red arrow). (C) Complete AV closure (red arrows). Reprinted from Estep et al. with permission of the publisher. Copyright ©2010 Elsevier.<sup>14</sup>

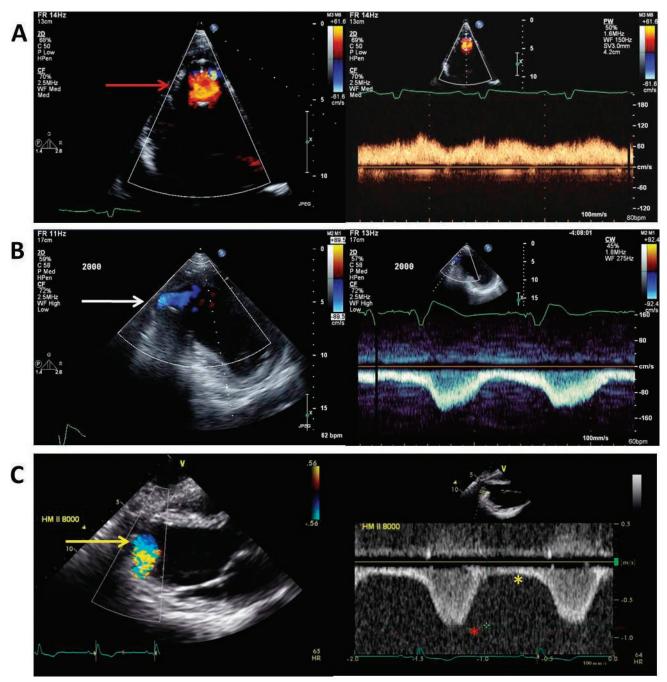


Figure 6. Normal continuous left ventricular assist device apical inflow cannula color and spectral Doppler. (A) Standard 4-chamber apical view illustration of nonturbulent, nonaliasing apical cannula inflow with color Doppler (red arrow) and slightly pulsatile, low peak velocity (< 1.5 m/s) continuous flow directed towards the apical transducer. (B) "Off axis" 2-chamber apical view of an inferiorly positioned apical inflow cannula (white arrow) with normal flow characteristics (slightly pulsatile, low peak velocity) similar to panel A with the exception of continuous flow directed away from the apical transducer. Red asterisk shows peak systolic apical inflow velocity; yellow asterisk shows peak diastolic apical inflow velocity. (C) Parasternal long-axis view of normal apical cannula inflow color Doppler (yellow arrow) and pulse-wave Doppler flow characteristics with continuous flow directed away from the apical transducer similar to panel B. Reprinted from Estep et al. with permission of the publisher. Copyright ©2010 Elsevier. 14

Pericardial effusion with or without cardiac tamponade

Left ventricular (LV) failure secondary to partial LV unloading (increased mitral inflow peak E wave diastolic velocity, increased E/A and E/e' ratio, decreased deceleration time of mitral E velocity, increased left atrial volume, worsening functional mitral regurgitation, and elevated pulmonary artery systolic pressure)\*

Right ventricular (RV) failure (increased RV size, decreased RV systolic function, increased right atrial pressure, increased tricuspid regurgitation, interatrial septum shifted to the left, reduced RV outflow tract stroke volume, reduced spectral Doppler of LVAD inflow and outflow velocities, i.e., < 0.5 m/sec with severe failure)

Inadequate LV filling or excessive LV unloading (small LV dimensions and/or marked deviation of the interventricular septum towards the LV)

LVAD suction and/or induced ventricular ectopy or tachycardia (under filled LV and mechanical impact with endocardium)

LVAD-related continuous aortic insufficiency (aortic regurgitation throughout cardiac diastole and systole; at least moderate to severe severity characterized by a regurgitant jet to LV outflow tract height ratio > 47%, relative decreased RV outflow tract stroke volume, and increased LV size)

LVAD-related mitral regurgitation (MR) (posterior malpositioned inflow cannula with incomplete mitral valve coaptation secondary to posterior leaflet tethering and moderate to severe MR)

Intracardiac thrombus (including right and left atrial, LV apical, and aortic root thrombus)

Apical inflow abnormality due to inflow cannula obstruction, malposition, or hyperdynamic apical LV function (color Doppler high-velocity aliased flow at the cannula orifice with a peak Doppler velocity > 2 m/s)

Outflow cannula kinking or complete thrombosis (partial-elevated peak outflow cannula velocity > 2 m/s; complete loss of Doppler signal and no RV outflow tract stroke volume increase and/or no decrease in LV linear end-diastolic diameter dimension with pump speed increases)

Hypertensive emergency, continuous-flow pump (minimal AV opening, dilated LV, worsening MR, and peak outflow cannula velocity > 2 m/s)

Pump malfunction -Impeller dysfunction/cessation (dilated LV, acute reversal of apical inflow flow direction using spectral or color Doppler, worsening MR, and decreased RV outflow tract stroke volume; and/or no decrease in LV linear end-diastolic diameter dimension or reduction in AV opening with pump speed increases)

Table 7. Continuous-flow LVAD post-implant complications and device dysfunction detected by echocardiography. Reprinted from Estep et al. with permission of the publisher. Copyright ©2010 Elsevier.<sup>14</sup>

II device, a power trend increase greater than 2 watts or a consistent reading greater than or equal to 10 watts in the setting of an unchanged pump speed is a red flag for possible rotor thrombosis. The displayed pulsatility index reflects contraction of the LV and hence LV contribution of flow into the pump. The magnitude of these flow pulses is measured by the pump and is averaged over a 15-s interval to produce the displayed pulsatility index (PI) value.

Pump parameter deviations and identified alarms should be placed in clinical context. The clinical symptoms and signs along with the type of LVAD alarm findings will guide the diagnosis and treatment recommendations. In general, alarms can be classified as either a low-flow or high-power (high-flow) alarm. For the HeartMate II device, low-flow alarms may be associated with or defined by one or more of the following signs: decreased pulsatility index (PI), PI event (a 45% ± change from the previous 15-s running average), low-flow alarm display, or flow display "---" noted as the flow estimate. LVAD suction events relate to contact of the inflow cannula and the LV endocardium. which results in a decrease in inflow cannula flow and can be associated with a change in clinical status and/or LVAD function. LVAD suction events can be seen with hypovolemia, right ventricular failure, cardiac tamponade (typically not seen in the outpatient setting), or inflow cannula malposition and may be associated with atrial and/or ventricular arrhythmias. The underlying treatment recommendations are specified in Tables 3 and 4.

### **Blood Work Surveillance Testing**

As for any patient with underlying heart failure, we perform a thorough history, review of symptoms including device-specific questions (Table 5), and physical exam. We also obtain the following surveillance lab blood work with each clinic visit: complete blood count, complete metabolic profile, international normalized ratio, and lactate dehydrogenase (LDH). Patients on CF-LVAD support are at risk for infection, hemolysis due to rotor pump thrombosis, and gastrointestinal bleeding; therefore, it is important to screen for acquired leukocytosis, elevation in serum markers representing red blood cell disintegrity (e.g., LDH and/or serum free hemoglobin), and a decrement in hemoglobin.

The clinical symptoms, signs, and other associated lab findings should help distinguish between hemolysis and gastrointestinal bleeding. Hemolysis may be characterized by dark urine, hemoglobinuria defined by urine analysis with large quantitative blood and few-to-no urine red blood cells, *lactate dehydrogenase* (*LDH*) level greater than 2.5-times upper limits of normal, increasing total bilirubin, and elevated serum free hemoglobin. Shah et al. showed that an elevated serum LDH was more predictive of device thrombosis than the INTERMACS-defined threshold of 40 mg/dL for serum free hemoglobin. Cowger et al. expanded these findings by demonstrating that an LDH-based definition of hemolysis (greater than 2.5-times reference range maximum) was also superior to the INTERMACS definition for predicting thrombus-related events. In our patient population, an LDH level greater than 1,050 IU/L was associated

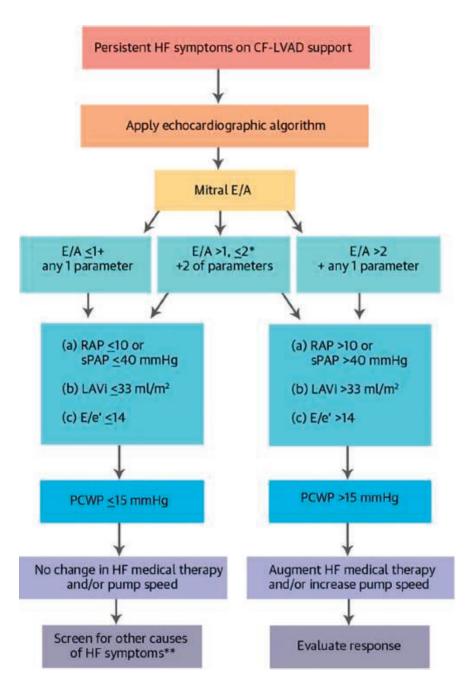


Figure 7. Algorithm for continuous-flow left ventricular assist device (CF-LVAD) persistent heart failure symptom evaluation. \*In the presence of fused or indistinct E and A signals, two of three parameters must be met and concordant. \*\*Other echo findings are nondiagnostic (e.g., no pericardial effusion). Augmentation in heart failure medical therapy and/or increase pump speed should be discussed with the implanting LVAD heart team. Reproduced by permission Estep et al.<sup>15</sup>

with a sensitivity and specificity of 80% and 86% to detect device thrombosis and malfunction and is similar to the LDH cutoff (1,103 IU/L) reported by Uriel et al. as an indicator for device thrombosis. <sup>11,12</sup> Haptoglobin has been less useful as a parameter in that it is commonly low as demonstrated in our cohort of stable patients on CF-LVAD. <sup>11</sup> In the absence of signs of hemolysis, a decrement in hemoglobin should prompt concern and an evaluation for a gastrointestinal bleed.

# **Echocardiography Surveillance (Image Acquisition and Reporting)**

Echocardiography is the primary imaging modality to monitor patients supported by LVADs. <sup>13,14</sup> Given the clinical implications of the type of LVAD and pump speed on heart function, these parameters should be recorded in the echo report. In our practice,

the comprehensive LVAD exam (obtained at 1, 3, 6, and 12 months post-LVAD implant) consists of a standard echocardiographic examination (Table 6), recording several cardiac cycles to assess ventricular dimensions and AV function (Figure 5), visualization of apical inflow cannula with Doppler, assessment of peak systolic and diastolic inflow velocity (Figure 6), and a complete LV diastolic function assessment based on the transmitral Doppler inflow pattern (peak early and late velocity and deceleration time), septal and lateral mitral valve annular velocities, left atrial volume, and right atrial and systolic pulmonary artery pressure.<sup>15</sup>

Our approach for assessing a patient on a CF-LVAD with recurrent HF symptoms, dysrhythmias, or a positive LVAD alarm history is based on an integrated clinical exam, device alarm interrogation, and device-specific echocardiographic findings. Table 7 lists CF-LVAD post-implantation complications (i.e.,

Patient name:						Discharge	date after L	VAD implant	t:	
Device type:										
Indication: Bridge to transplant destination therapy										
Date of implant:										
Cardiomyopathy type: Nonischemic	Ischemic					VAD emerg	gency line:			
Clinic follow-up	Year:									
schedule from date	Month:									
of discharge:		1 month	2 month	3 month	4 month	6 month	8 month	12 month	15 month	Every 6 months
Vital signs to include: Doppler BP assessment (see algorithm)		X	X	Х	X	X	X	X	Х	X
LVAD clinic visit: phys exam	ical	X	X	X	X	X	X	X	Х	X
LVAD interrogation		X	X	X	X	Х	Х	X	X	Х
Inspect driveline exit s	ite *	Х	X	Х	Х	Х	Х	X	X	Х
Check equipment		X	X	X	Х	Х	Х	X	Х	Х
Labs:  CBC w/ diff  Basic metabolic panel  BNP  LFTs  LDH  INR  Fasting lipid panel (annually)  HgB A1C (if diabetic) –  every 6 months		X	X	X	X	X	X	X	X	X
EKG X		Х	Х	Х	Х	Х	Х	Х	Х	
Echocardiogram		Х		Х		Х		Х		annually
Interrogate ICD/ PPM		Х								annually

<sup>\*</sup> Retention suture at driveline exit site should be intact/ present until 3 months post implant. It will be removed at LVAD center with surgical visit. BP: blood pressure; CBC w/diff: complete blood count; BNP: brain natriuretic peptide; LFTS: liver function tests; LDH: lactate dehydrogenase; INR: international normalized ratio; EKG: electrocardiogram; ICD: intracardiac device; PPM: permanent pacemaker.

 Table 8. Houston Methodist Physician Partnership follow-up protocol. Orange highlight notes follow up schedule and physician partnership responsibilities.

acquired continuous aortic insufficiency and LVAD-related suction events) and the associated echocardiographic criteria we use to guide echo reporting. Many of these clinical challenges can be significantly influenced by the underlying baseline pump speed setting, excessive afterload (occult hypertension), and the inflow cannula position/mal-position.

Persistent or acquired HF symptoms (New York Heart Association class III/IV) while on CF-LVAD support may be due to partial LV unloading and/or right-sided HF. We recently demonstrated how Doppler echocardiography accurately estimated intracardiac hemodynamics in 50 patients supported with the HeartMate II LVAD. <sup>15</sup> Our algorithm reliably distinguished normal from elevated LV filling pressures. The echo-based algorithm we derived to detect underlying partial LV unloading (i.e., pulmonary capillary wedge pressure > 15) is illustrated in Figure 7. We recommend that providers consult with the LVAD implanting center heart team if a patient has a clinical indication that warrants changing the underlying pump speed—for example, increasing the underlying pump speed if partial LV unloading or associated HF symptoms/signs are

detected, or decreasing the pump speed if LVAD suction events are detected).

#### **Conclusions**

Newer-generation CF-LVADs such as the HeartMate II device have gained widespread recognition and use. Given the continued support needed by patients on this type of device, standardized outpatient follow-up with clearly defined objectives (Table 8, 9) and shared care responsibilities between the implanting LVAD heart team and care providers in the community are necessary to facilitate the long-term management needed by many of these patients.

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Keywords: continuous flow LVAD, left ventricular assist device, heart failure, shared care

Driveline Exit Site:	Equipment Check:
☐ Clean, Dry, Intact	☐ Patient demonstrates daily controller self-test
☐ Skin adhered (driveline)	☐ No obvious damage to power lead pins
□ Redness	☐ Driveline intact
☐ Induration	☐ Back-up controller settings confirmed
☐ Drainage	☐ Back-up controller battery charged
☐ Tear / Trauma to exit site	☐ Equipment concerns/
□ Pain	damage communicated to VAD center/manufacturer
Check:	
☐ Immobilization device in use (anchor or belt)	

Table 9. Clinic visit documentation.

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